HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

T 1937M

4298 Elysian Fields Avenue
New Orleans, LA 70122
Telephone (504) 589-6341

July 23, 1998

WARNING LETTER NO. 98-NOL-28

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert A. Stroud, President
Medical Equipment Company, Incorporated
1532 River Oaks West
Harahan, Louisiana 70123

Dear Mr. Stroud:

During an inspection of your firm, located at 1532 River Oaks West, Harahan, Louisiana, on May 22 and 26, 1998, our investigators determined that your firm is registered as an Initial Medical Device Distributor. Your firm also is a specifications developer and own label distributor of convenience kits for Anesthesia, Respiratory Therapy, Critical Care Nursing and Infection Control. The ventilator tubes, breathing bags, gas sampling lines, airways, endotracheal tubes, catheters, and other products listed in your catalog are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) regulations for Medical Devices, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820, and the Quality System Regulations, 21 CFR 820, which became effective June 1, 1997, as follows:

(1) Failure to establish a quality system plan to control and describe the overall design process as required by 21 CFR 820.30(b);

(2) Failure to document audits or oversight of contract manufacturers as required by 21 CFR 820.50(a);

(3) Failure to have a master record with initial component and finished product specifications as required by 21 CFR 820.18(a-e); and,

(4) Failure to have a sampling plan or test product before distribution as required by 21 CFR 820.80(d) and 820.250(a).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all warning letters about devices, so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approvals (PMA's) or export approval requests will be approved and no premarket notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured at the facility in which the above CGMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Carolyn S. Olsen, Compliance Officer, 4298 Elysian Fields Avenue, New Orleans, LA 70122-3896. Should you have any questions concerning the contents of this letter, or desire a meeting with the Agency staff, please contact Ms. Olsen at (504) 589-7166.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

/ker